



800 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

December 10, 1996

97-PHI-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Samuel Dixon, Jr.
4516 Sudlersville Road
P.O. Box 1182
Clayton, DE 19938

Dear Mr. Dixon:

GEN.	SPEC.
RELEASE	
F#	DATE: 12/12/96
Reviewed by: <i>[Signature]</i>	

An inspection of your dairy farm located on 4516 Sudlersville Road in Clayton, Delaware, conducted by Food and Drug Administration (FDA) investigators Gerald W. Kopp and Joseph L. Despina on October 21, 1996, confirmed that you offered a cow for sale for slaughter for human food in February 1996 in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about February 7, 1996, you sold a cow, back tag #51BES107 and ear tag #CV06233, for slaughter as human food at ~~XXXXXXXXXX~~, ~~XXXXXXXXXX~~ United States Department of Agriculture (USDA) testing of the animal revealed the presence of 1.2 ppm penicillin in its kidney tissue. This is considered to be an illegal tissue residue since the tolerance for penicillin in edible bovine tissue is 0.05 ppm. The presence of penicillin in the edible tissue from your animal at the concentration level detected renders the food from the animal to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

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Our inspection revealed that your herdsman, Cheryl W. Vest, treated the subject cow with [REDACTED] and [REDACTED] because the cow developed mastitis and bag blowout. She indicated during the inspection that she held the cow for the prescribed withdrawal period before offering the cow for slaughter for human food. The 1.2 ppm penicillin residue, however, indicates that either the recommended dosage was exceeded or the labeled pre-slaughter withdrawal period was not followed.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Very Truly Yours,



Diana J. Kolaitis
District Director
Philadelphia District

jci

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Enclosure: FDA-483 dated 10/22/96 issued to Cheryl W. Vest,
Herdsman, Dixon Farm

cc: Dr. Max A. Van Buskirk, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

cc: Dr. F.R. Rellosa
USDA Northeast Regional Office
701 Market Street
2B South
Mellon Independence Center
Philadelphia, PA 19102-1516